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11  
12 **UNITED STATES DISTRICT COURT**  
13 **DISTRICT OF NEVADA**

14 \* \* \* \* \*

15 IN RE: HCV PRISON LITIGATION

Case No: 3:19-cv-00577-MMD-CLB

16 **RESPONSE TO QUARTERLY REPORT**  
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18  
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20 Class Counsel submits this Response to Defendant's Quarterly Report (ECF No. 108) and  
21 pursuant to the Consent Judgment (ECF No. 80).

22 **MEMORANDUM OF POINTS AND AUTHORITIES**

23 **I. INTRODUCTION**

24 One year after the Consent Decree, Class Counsel is pleased to report that 638 class  
25 members have been cured or have begun receiving the cure for chronic Hepatitis C.<sup>1</sup> This  
26 represents more than a six-fold increase over the number of class members who were treated  
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<sup>1</sup> All data referenced herein is based on information provided by Defendants.

1 annually prior to this litigation. At the conclusion of this period, Class Counsel have extensively  
2 reviewed the materials provided by Defendants and believe them to be in technical compliance  
3 with the obligations of the Consent Decree. However, based on these same materials, Class  
4 Counsel have concerns with compliance with the spirit of the Consent Decree and with  
5 Defendants' obligations going forward.

6 First, there continue to be ongoing issues with the timely delivery of monitoring  
7 information to Class Counsel. After multiple communications attempting to secure the early  
8 provision of data, on October 28, 2021, one day before the deadline for the quarterly report,  
9 Defendants provided class counsel with 15 spreadsheets and 198 PDF documents containing the  
10 requested information. The provision of additional data continued through November 19, 2021.  
11 While Class Counsel appreciate receiving the volume of information and the effort it took  
12 Defendants to compile and provide it, this amount of data requires a significant amount of time to  
13 analyze and to evaluate.

14 Second, as frequently repeated, the paramount issue for Class Counsel remains the number  
15 of inmates who ultimately receive DAA treatment. The Consent Decree required that 1,200  
16 inmates would receive DAA treatment by October 29, 2021. While this number was based on an  
17 overestimate of inmates with HCV and was not reached by Defendants, so long as every eligible  
18 inmate received DAA treatment this would constitute substantial compliance. However, based on  
19 parsing the data received from Defendants, there are still a significant number of inmates who  
20 could have received treated at some point during the twelve-month period but were released prior  
21 to receiving treatment. If sequenced earlier, they could have been released after being cured.

22 Below, Class Counsel ask for confirmation of certain informational items and ask for one  
23 substantive change to the Consent Decree: class members with positive antibody tests should  
24 receive a confirmatory viral test within three months and then should begin DAA treatment (if  
25 eligible and unless they refuse) within three months after the confirmatory test. Given the  
26 dramatically lower of identified cases, this rate of treatment should not pose any hardship to  
27 Defendants as their financial and administrative burden is still far less than expected upon entry  
28 into the Consent Decree.

## II. CONSENT DECREE REQUIREMENTS

This section is intended to provide the Court with a brief recap of Defendants' obligations under the Consent Decree an evaluation of the same.

**Policy** – “Defendants agree to adopt and follow the revised version of MD 219, attached and incorporated as Appendix A, and the revised version of the HCV Consent Agreement, attached and incorporated as Appendix B.” ECF No. 80, ¶ 29. This was accomplished by Defendants. ECF No. 84, Quarterly Report, Jan. 29, 2021.

**Policy** – “Defendants agree not to use any nonmedical reason to deny class members DAA Treatment, or delay DAA Treatment except as specified in Appendix A or Appendix B.” ECF No. 80, ¶ 30. Class counsel have not identified any instances of this occurring.

**Policy** – “Defendants will not modify or replace MD 219 or the HCV Consent Agreement during the time frame in which this Consent Decree is in force, without approval of the Court.” ECF No. 80, ¶ 31. This has not occurred to the knowledge of Class Counsel.

**Testing** – “Defendants agree to test all inmates in the custody of NDOC for HCV by December 31, 2020.” ECF No. 80, ¶ 32. This was accomplished by Defendants. ECF No. 84, Quarterly Report, Jan. 29, 2021.

**Testing** – “Defendants will continue to test all inmates for HCV during the intake process, unless an inmate refuses or choose to opt-out of the testing.” ECF No. 80, ¶ 33. This has been accomplished by Defendants. ECF No. 84 (testing of 803 inmates, returning 120 positive tests); ECF No. 86 (testing of 806 inmates, returning 76 positive tests); ECF No. 103 (testing 1,122 inmates, returning 74 positive tests); ECF No. 108 (testing 1,174 inmates, returning 90 positive tests).

**Testing** – “By January 11, 2021, Defendants will screen and prioritize all Class Members using the criteria in the revised version of MD 219, attached as Appendix A.” ECF No. 80 ¶ 34. This was accomplished by Defendants. ECF No. 84, Quarterly Report, Jan. 29, 2021. Moreover, this issue has effectively been rendered moot as Defendants have broadly treated the Class Members such that prioritization is no longer at issue. ECF No. 100-1, Minev Declaration, June 25, 2021 (“I have instructed all staff to proceed, as expeditiously as possible, with all treatment,

1 regardless of priority level so that all may be treated. This will allow a more expeditious use of  
 2 resources at institutions where all of the priority one inmates have begun the treatment protocol.”)

3 **Treatment** – Defendants agreed to provide DAA treatment to a minimum of “1,200 Class  
 4 Members” by October 29, 2021. ECF No. 80 ¶ 36. This did not occur but Defendants have  
 5 represented that they have treated all eligible inmates.

6 **Monitoring** – Defendants have agreed to timely provide certain information to Class  
 7 Counsel and the Court. ECF No. 80 ¶ 40. Defendants have provided the requested information.  
 8 However, Class Counsel continue to have issues with obtaining this information “in a reasonably  
 9 usable and accessible format on a timely basis.” *Id.* ¶ 41.

### 10 **III. TESTING ISSUES AND ANALYSIS**

11 The number of inmates with chronic HCV and who are interested in and eligible for  
 12 treatment has proved far lower than expected based on information received from NDOC. Initially,  
 13 based on discovery responses and estimates provided by Defendants, Class Counsel expected the  
 14 number of class members with HCV in NDOC custody to total approximately 2,400. ECF No. 86  
 15 ¶ 35 (“Defendants represent and warrant that, to the best of their current knowledge, as of the  
 16 Effective Date there are fewer than 2,400 inmates in NDOC custody who have chronic HCV”).  
 17 As of March 11, 2020, Defendants had identified 1,114 class members in NDOC custody that had  
 18 been diagnosed with HCV and this number was based on only partial testing of the inmate  
 19 population.

20 In the first Quarterly Report on January 29, 2021, Defendants identified “745 inmates as  
 21 HCV positive.” ECF No. 84, 5. An additional 76 inmates tested positive in the second Quarterly  
 22 Report between January 29, 2021 and April 13, 2021. ECF No. 86, 3. In the third Quarterly Report,  
 23 an additional 74 inmates tested positive and in the fourth Quarterly Report there were an additional  
 24 90 inmates who tested positive. ECF Nos. 103, 106. Defendants question how Class Counsel  
 25 arrived at the number (810) of Hepatitis C positive inmates in the third Quarterly Report and  
 26 contend that this number is incorrect. ECF No. 108, n.1. As previously indicated by Class Counsel,  
 27 this was an approximation based on the limited information provided by Defendants that reflected  
 28 the additional positive tests. *See* ECF No. 84, 86, 106 (identifying 745 inmates as HCV positive in

1 January 2021, an additional 76 inmates who tested positive by April 13, 2021 and an additional  
2 who 74 inmates tested positive by July 27, 2021).

3 The discrepancy between the initial positive HCV cases and the “current working number  
4 of positive HCV inmates” was partially explained by Defendants because while there were “1,414  
5 inmates with HCV positive antibodies” only “745 of them have a viral load.” ECF No. 94.  
6 Essentially, the higher initial numbers were based on an antibody test that only indicated whether  
7 HCV was generally detected whereas the subsequent RNA (viral load) test indicated whether there  
8 was a current HCV infection. *See, e.g.,* [https://www.hcvguidelines.org/evaluate/testing-and-](https://www.hcvguidelines.org/evaluate/testing-and-linkage)  
9 [linkage](https://www.hcvguidelines.org/evaluate/testing-and-linkage). Pursuant to the prevalent medical guidance, DAA treatment would not be appropriate for  
10 the inmates who did not have a current, active, and chronic infection. *Id.*

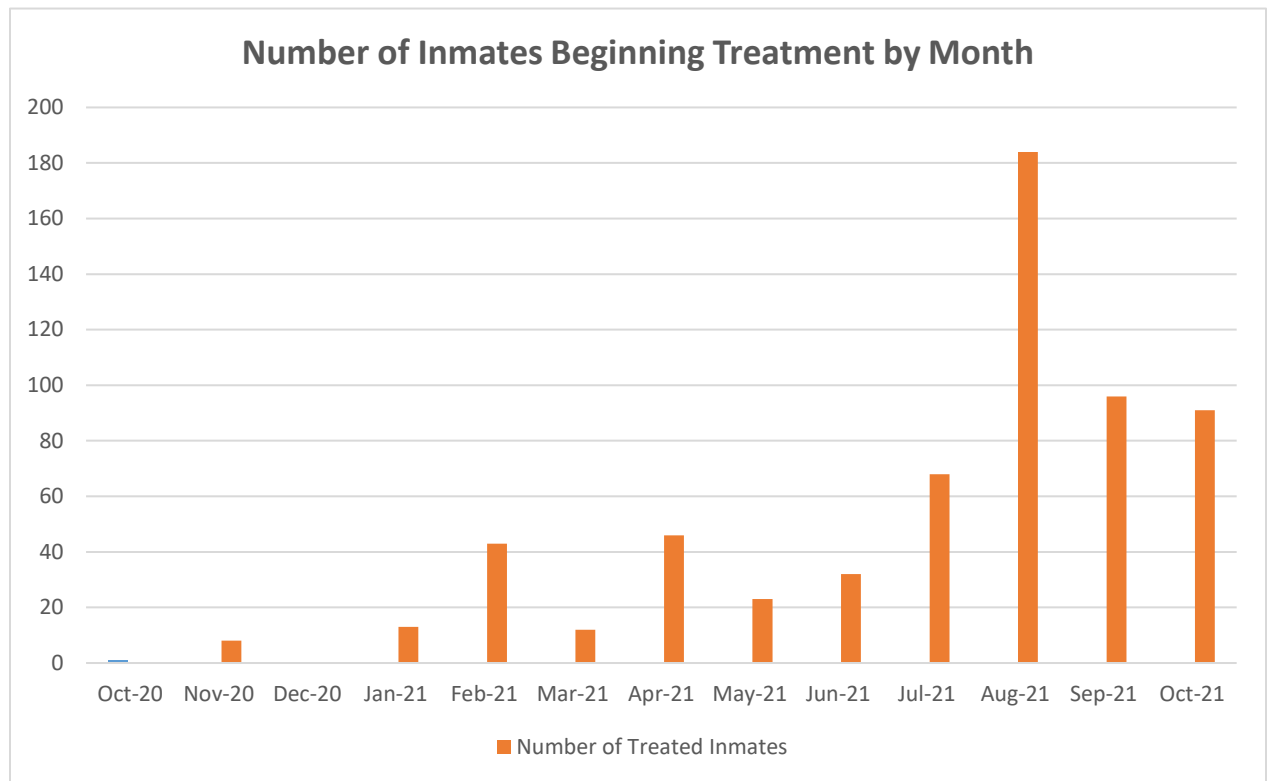
11 There is also another explanation though for the discrepancy between the expected number  
12 of positive cases among the NDOC population and the actual number identified. Defendants have  
13 identified approximately 927 inmates who refused testing. In order to reduce the number of class  
14 members who opt-out of HCV testing and to ensure that the decisions to refuse testing were  
15 informed, Class Counsel proposed the provision of additional information about HCV testing and  
16 treatment and Defendants have accepted and implemented this proposal. ECF No. 103, 7. The  
17 precise date on which this additional educational information began to be provided is not certain  
18 to Class Counsel. Of the approximately 927 inmates who have refused testing though, there are  
19 approximately 11 who signed two refusals prior to March 24, 2021 during which time the  
20 educational information about HCV was inadequate. Thus, these 11 individuals should be provided  
21 with the revised educational information and be provided with a meaningful opportunity to accept  
22 testing for HCV. There are a further 202 inmates who signed two refusals and the latter of the  
23 refusals was signed on or after June 28, 2021. An additional 52 inmates only signed one refusal,  
24 but which was after June 28, 2021. If Defendants can confirm that this date was after the provision  
25 of revised educational information, then no further action appears to be warranted for these  
26 individuals.

27 There are, however, a significant number of inmates who still have not been provided with  
28 adequate educational information about HCV in order to meaningfully opt-out of testing. There

are approximately 662 inmates who opted-out of testing prior to June 28, 2021 and should receive an additional opportunity to opt-in after receiving the revised educational information about HCV.

#### IV. TREATMENT ISSUES AND ANALYSIS

As of October 29, 2021, approximately 296 inmates had completed DAA treatment and 342 were in the middle of receiving DAA treatment. ECF No. 108 (Defendants' report does not include 20 released inmates who completed DAA treatment prior to being released, thus the difference between 276 inmates reported by Defendants and the 296 herein). While this would be a violation of the Consent Decree, ECF No. 80, as fewer than 1,200 inmates have been treated, if Defendants have treated the entire eligible population then Class Counsel would consider them in compliance in this aspect. The following graph, based on information provided by Defendants, depicts the chronology of DAA treatment provided to the class members, totaling 616 (not including the 20 released inmates and 2 inmates with missing start dates).



1           The above graph illustrates that Defendants greatly accelerated the rate of treatment in  
 2 advance of the October 29, 2021 deadline. Putting aside certain undisputed categories of inmates  
 3 who have not received treatment, such as those with medical contraindications<sup>2</sup>, there are two main  
 4 categories that require addressing: inmates who refused treatment and inmates who were released.  
 5 Taking into consideration these categories, there have actually been approximately 1,423 inmates  
 6 in NDOC custody in the previous twelve-months who have been HCV positive, which is a more  
 7 accurate approach than the single-point-in-time approach used by Defendants to identify 737  
 8 inmates.

9           First, based on data and documentation recently provided by Defendants, there are 202  
 10 inmates who have signed two refusals, the latter of which was on or after June 28, 2021 and 52  
 11 inmates who have only signed one refusal but which was after June 28, 2021. If Defendants can  
 12 confirm that the refusals signed after June 28, 2021 were based on full information, then no further  
 13 action appears to be warranted for these 202 individuals. Alternately, these dates and the affected  
 14 population can be adjusted based on the date that Defendants provided the revised information.  
 15 However, of the remaining portion of the approximately 927 inmates who have refused testing  
 16 though, Defendants will need to confirm that their refusals were based on full information.

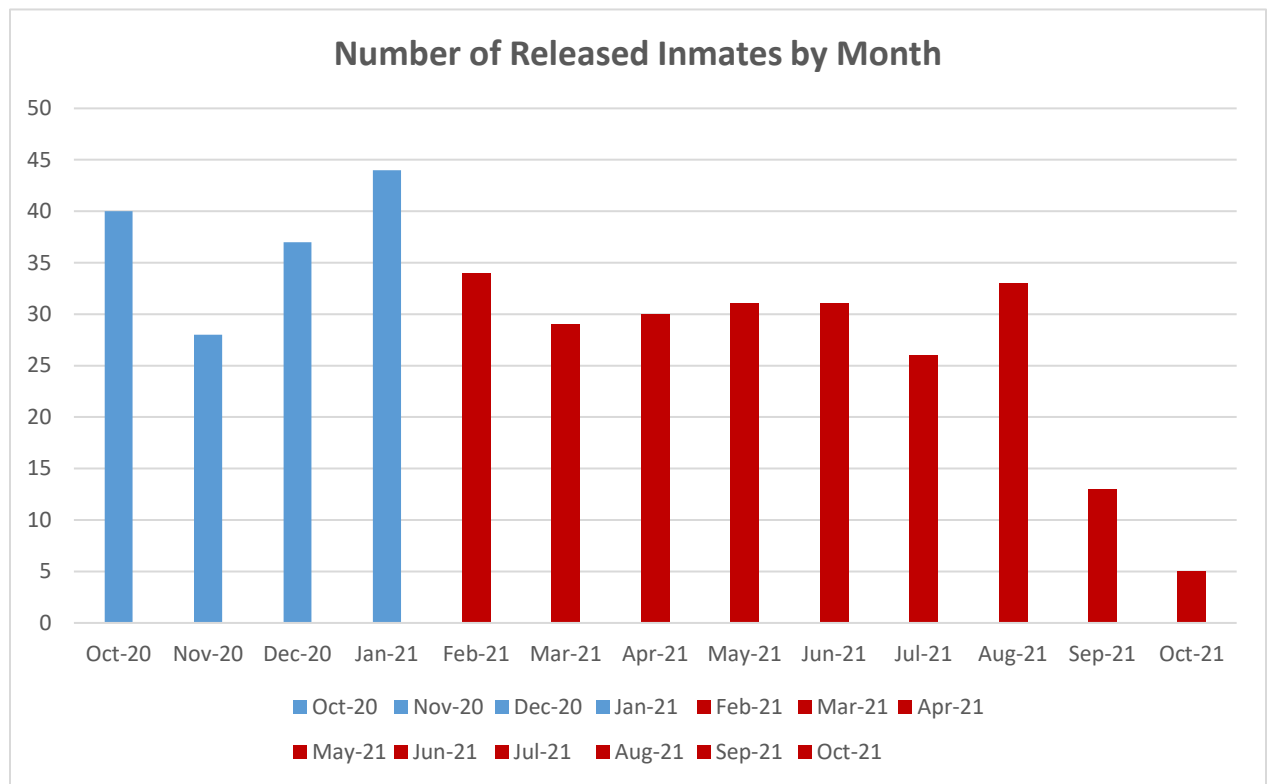
17           Second, there are 105 inmates with chronic HCV who have refused treatment. Class  
 18 counsel have requested and reviewed the refusal forms executed by these individuals. The majority  
 19 of these forms were executed after June 2021, which is around the date that Defendants began  
 20 providing revised educational information to the inmates. Additionally, the reasons listed for  
 21 refusal, when available, are generally outside of the Defendants' control – such as a desire to  
 22 receive treatment once released from custody or to have treatment provided by the Veteran's  
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25 <sup>2</sup> Class Counsel continues to be concerned though that some of the inmates have become ineligible  
 26 for treatment due to unconstitutional delays in receiving treatment. See  
 27 <https://www.hcvguidelines.org/evaluate/when-whom> (“Initiating therapy in patients with lower-  
 28 stage fibrosis augments the benefits of SVR” . . . “A modeling study based on the Swiss HIV  
 cohort study also demonstrated that waiting to treat HCV infection until Metavir fibrosis stages F3  
 and F4 resulted in 2- and 5-times higher rates of liver-related mortality, respectively, compared  
 with treating at Metavir stage F2.”

Administration after release.<sup>3</sup> However, there are at least 15 inmates who refused treatment prior to the revisions to the educational information. As these individuals are known to have chronic HCV and would receive the most benefit from treatment, it is imperative that any inmate who refused prior to receiving the revised educational information be provided with it and with another opportunity to opt-in to treatment if they continue to fall within the MD 219 guidelines.

Third, there are approximately 638 inmates with chronic HCV who were released prior to receiving treatment and an additional 28 inmates with chronic HCV who were released after beginning treatment but prior to receiving it. The latter category merits special attention as there can be serious medical consequences for beginning DAA treatment without finishing it. Further explanation is required for the timing of these inmates' treatment and release. On the inmates who were released prior to receiving treatment, Class Counsel analyzed these releases to determine if there was any improper pattern, but they are evenly distributed between December 2020 and October 2021.



<sup>3</sup> There were certain refusals based on a concern about receiving treatment at a different facility. Class Counsel would encourage Defendants to accommodate these requests.

Based on this analysis, Class Counsel have not identified any pattern of note for the timing of the releases that suggest intentionality. However, the red columns in the graph above represent inmates who could have completed treatment if they had started at the beginning of the period. MD 219.05 provides: “Insufficient time remaining on the sentence to complete DAA treatment. Insufficient time is defined as fewer than 120 days remaining on the sentence in NDOC.” ECF No. 80. Accordingly, Defendants should not be permitted to delay treatment for these individuals until they have fewer than 120 days remaining on their sentence. There are approximately 232 additional inmates who could have completed DAA treatment but were released toward the end of the time period. Class Counsel has confirmed through cross-referencing the information provided by Defendants against public records, available at <https://ofdsearch.doc.nv.gov/>, that at least the selection of inmates reviewed were in custody at the beginning of the time period and could have received treatment in October 2020. There may be some inmates though who were not in custody until later in the time period.

#### V. STANDARD OF CARE

Class Counsel’s position on the standard of care is the same as Defendants, and Class Counsel has not identified any changes to the medical standard of care for HCV that would warrant alterations of the Consent Decree. The HCV Guidelines of the AASLD and the IDSA were last updated on September 29, 2021, and continue to recommend direct-acting antiviral treatment. <https://www.hcvguidelines.org>. Based on these latest updates, which primarily include a switch for elbasvir/grazoprevir (not currently used by Defendants) from a recommended regimen to an alternative regimen for certain genotypes, no additional changes are necessary to MD 219.

#### VI. TRANSITION TO RATE-BASED TREATMENT

Pursuant to Paragraph 38 of the Consent Decree, after the expiration of thirty-six months and after 2,400 inmates received treatment, Defendants agreed “to provide DAA treatment to Class Members within NDOC’s custody at a rate that, at a minimum, exceeds the HCV infection rate of new inmates who test HCV positive, or who are confirmed to be HCV positive, during the intake process. For the avoidance of ambiguity, if an additional 600 inmates tested positive for HCV

1 during intake in one calendar year, then Defendants agree to provide DAA treatment to at least  
 2 600 Class Members in the same calendar year.” ECF No. 80, ¶ 38.

3 As explained above, due to the significant difference in the expected number of inmates  
 4 needing treatment versus the actual number, Class Counsel requests that rather than continue on  
 5 with the quantitative metric (e.g. 600 inmates in the next twelve months), the standard of Paragraph  
 6 38 should be accelerated so that Defendants must provide treatment at a rate equal to the number  
 7 of new inmates who test positive.<sup>4</sup> Class Counsel also requests that Defendants make good faith  
 8 efforts to expedite treatment of new inmates who test positive. The accelerated activity over the  
 9 last few months shows Defendants can quickly provide treatment.

## 10 VII. CONCLUSION

11 Class Counsel requests that by the next quarterly report deadline, Defendants confirm the  
 12 following: 1) the date on which revised educational materials began to be provided and became  
 13 standard; 2) that the inmates who refused treatment have been provided with the revised  
 14 educational materials and with another opportunity to opt-in to treatment; and 3) that the inmates  
 15 who refused testing without receiving the revised educational materials have been provided with  
 16 the revised educational materials and with another opportunity to opt-in to testing.

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28 <sup>4</sup> The goal of 600 inmates is almost certainly unattainable because there are not 600 inmates with HCV remaining in NDOC custody and willing to receive treatment.

1 Class Counsel also request that the Consent Decree be modified to require that class  
2 members with positive antibody tests must receive a confirmatory viral test within three months  
3 and then must begin DAA treatment (if eligible and unless they refuse) no later than three months  
4 after the confirmatory test.

5  
6 Dated November 23, 2021.

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7  
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